UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE: DA VINCI SURGICAL ROBOT ANTITRUST LITIGATION	Lead Case No.: 3:21-cv-03825-VC
THIS DOCUMENT RELATES TO: ALL ACTIONS	
SURGICAL INSTRUMENT SERVICE COMPANY, INC., Plaintiff, vs. INTUITIVE SURGICAL, INC., Defendant.	Case No. 3:21-CV-03496-VC

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY
UNDER THE PROTECTIVE ORDER
VIRTUAL VIDEOCONFERENCE VIDEO-RECORDED
DEPOSITION OF TED CLAIBORNE

Monday, November 21, 2022
Remotely Testifying from Blue Point, New York

Stenographically Reported By:
Hanna Kim, CLR, CSR No. 13083
Job No. 5587024

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UNDER THE PROTECTIVE ORDER, virtual videoconference video-recorded deposition of TED CLAIBORNE remotely testifying from Blue Point, New York, on Monday, November 21, 2022, beginning at 1:04 p.m., EST, and concluding at 2:36 p.m., pursuant to the stipulations of counsel thereof, before Hanna Kim, CLR, Certified Shorthand Reporter, No. 13083.

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Also Present:

MICHAEL BARANKOVICH, Videographer

to Intuitive regarding that question; is that right?

A. Yes.

Q. The FDA's official advice was to "roll back use lives until the clearance"; is that right?

A. Yes. 02:00:15

Q. What does it mean to "roll back use lives until the clearance"?

A. It means to set the number of use lives to the number that was cleared in the prior 510(k).

Q. What was the number of use lives that was cleared in the prior 510(k)? 02:00:58

A. I think it's different for different instruments. I'd have to consult the file.

Q. Am I right that for each instrument, the number of use lives cleared in the prior 510(k) was lower than the number of lives in this current 510(k)? 02:01:40

A. Yes.

Q. You testified that the FDA's advice was "to set the number of use lives to the number that was cleared in the prior 510(k)."

Is that right? 02:02:11

A. Yes.

Q. Intuitive did not take that advice; correct? 02:02:30

MS. CAHOY: Objection to form.
BY MR. GLUBIAK:
Q. You can answer.
A. Well, as part of the call, the risk assessment on patient risk is made as well. And so, seeing that there is no increased risk to patients and given that we -- the 510(k) was in FDA's hands and under review, we felt that the patient risk was -- was unchanged and FDA indicated that they would use what's called an enforcement discretion while the 510(k) was under review. 02:02:48 02:03:18
Q. Intuitive did not set the number of use lives to the number cleared in the prior 510(k); correct?
A. You mean after this e-mail and call? 02:03:40
Q. Correct.
A. That's right.
Q. Was Intuitive in compliance with FDA regulations while it marketed extended-use EndoWrists during the FDA's review of its 510(k) application? 02:04:25
MS. CAHOY: Objection to form.
BY MR. GLUBIAK:
Q. You can answer.
A. Intuitive followed the regulations on when 02:04:35

to submit a 510(k) and their internal procedures to make that decision to not file a 510(k) for extended-use lives; and so, Intuitive believed it had followed the regulation, and that this was a disagreement between FDA and Intuitive on this topic. 02:05:16

MR. GLUBIAK: I think I'd like to take a quick break. If we could have about five minutes off the record. Is that okay, Kate and --

MS. CAHOY: Yes. 02:05:58

THE VIDEOGRAPHER: The time is 2:05. Going off the video record.

(Short recess taken.)

THE VIDEOGRAPHER: The time is now 2:20. Back on the video record. 02:20:47

BY MR. GLUBIAK:

Q. Mr. Claiborne, earlier you testified that sometimes during business meetings, you take notes in notebooks.

Do you remember that? 02:20:58

A. Yes.

Q. I believe you mentioned that one of the meetings during which you might have taken notes was the meeting you had with the 510(k) application team following your call with the FDA on December 23rd, 02:21:18

2021; is that right?
A. Yes.
Q. Mr. Claiborne, did you provide those notebooks to counsel as part of this case?
A. No. 02:21:41
Q. Mr. Claiborne, am I right that in 2020, Intuitive increased the number of uses on certain Xi instruments?
A. I don't know exactly when that happens. I think it was before I joined the company. 02:22:16
Q. But sometime before you joined the company, Intuitive increased the number of lives on certain Xi instruments; correct?
A. Correct.
Q. Intuitive submitted a 510(k) application regarding the extension of lives for those instruments in December of 2021; correct? 02:22:36
A. Correct.
Q. When Intuitive first increased the number of lives on those instruments, Intuitive used a non-filing justification for that extension; correct? 02:23:00
A. Yes.
Q. During the time between those non-filing justifications and the 510(k) application for those 02:23:22

EndoWrist instruments, was Intuitive in compliance with relevant FDA regulations?

MS. CAHOY: Objection to form.

BY MR. GLUBIAK:

Q. You can answer. 02:23:38

A. Intuitive followed their internal procedures and the -- when to submit 510(k) guidance and came to the conclusion that a letter to file was sufficient for that change. Ad so yes, they were following FDA regulation. 02:24:07

Q. Following the filing of that 510(k) application in December 2021, Intuitive continued to market extended-use EndoWrists; correct?

A. Yes.

Q. In the time period between the submission of that 510(k) application and the FDA's decision to grant 510(k) clearance for extended-use EndoWrists, was Intuitive in compliance with relevant regulations? 02:24:32

MS. CAHOY: Objection to form. 02:24:58

BY MR. GLUBIAK:

Q. You can answer.

A. Intuitive's interpretation of when to submit guidance had -- had not changed. They had gotten feedback from FDA. The FDA disagreed with 02:25:26

that decision and thought that there should be a 510(k) for that change. And so, it was Intuitive's belief that they were still in compliance.

Q. To -- it was Intuitive's belief that Intuitive was still in compliance even before it received the 510(k) clearance; correct? 02:26:14

MS. CAHOY: Objection to form.

THE WITNESS: I'm trying to think about how to formulate an answer [verbatim].

THE COURT REPORTER: I'm sorry. I can't hear you. 02:26:53

THE WITNESS: Can you repeat the question.

BY MR. GLUBIAK:

Q. Sure.

You just testified that during the period between the submission of the 510(k) application for extended-use EndoWrists and the FDA's decision to grant that application or to approve that application, it was Intuitive's belief that Intuitive was still in compliance with relevant regulations; is that right? 02:26:57 02:27:16

A. Correct. There was a difference of opinion between Intuitive and FDA on that letter to file or a so-called NFJ decision.

Q. That difference in opinion did not mean 02:27:46

that Intuitive was out of compliance with relevant regulations. Do I have that right?

MS. CAHOY: Objection to form.

THE WITNESS: No. My understanding is it meant that there was a compliance risk because of the difference of opinion. And that's why we wanted to call FDA and talk about it. 02:28:07

BY MR. GLUBIAK:

Q. Following this call, it was your understanding that the FDA would exercise its enforcement discretion not to take any enforcement action against Intuitive; is that right? 02:28:25

A. Yes, that was our understanding.

Q. Mr. Claiborne, I don't believe I have any other questions for you today. So I want to thank you for your time. 02:28:50

I don't know if my colleague, Mr. Van Hoven has a few questions but, you know, pending whether or not you get questioned by your own attorney, those are all the questions I have for now. 02:29:03

Thank you.

EXAMINATION

BY VAN HOVEN:

Q. Yeah. Hello, Mr. Claiborne. I -- I do 02:29:07